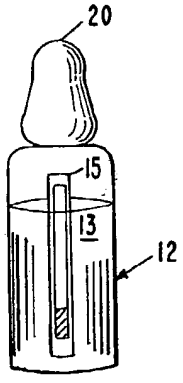

FIG-1

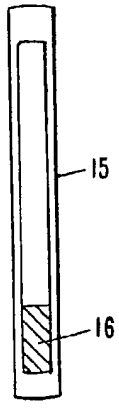

FIG-3

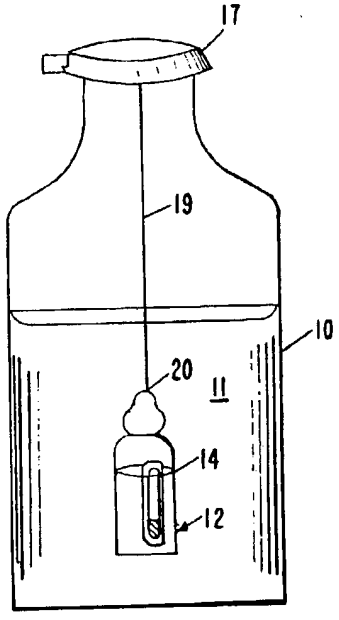

FIG-2

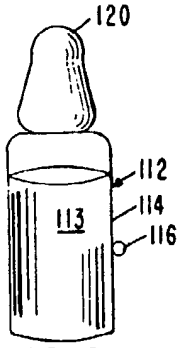

FIG.4

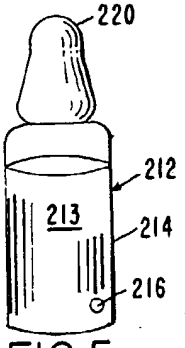

FIG.5

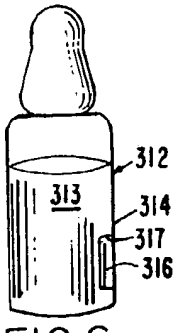

FIG.6

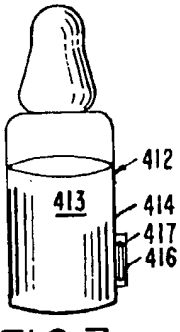

FIG.7

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(71) Applicant
American Sterilizer Co
(USA-Pennsylvania)
2424 West 23rd Street
Erie
Pennsylvania
United States of
America
(72) Inventor
Frank E Halleck
(74) Agent and/or Address for
Service
Carpmaels and Ransford
43 Bloomsbury Square
London WC1A 2RA

(54) Sterilization indicator

(57) A sterilization indicator that yields immediate visual post sterilization evidence of attainment of sterilization parameters by the change of a chemical indicator and time verification of destruction of spores by subsequent culture and incubation of organisms comprises a transparent container containing a liquid culture medium containing viable spores, indicator means for indicating the presence of viable spores on incubation of the culture medium and a temperature indicator for example a meltable pellet for indicating that a required sterilization temperature has been reached.

GB 2 113 389 A

SPECIFICATION

Sterilization indicator

The invention relates to the development of a specialized sterilization indicator that yields post sterilization evidence of attainment of certain sterilization parameters by: (1) the change of a chemical indicator to give immediate visual indication of achievemnt of the desired temperature, and (2) biological verification of the destruction of the spores contained therein by the subsequent incubation of these indicator organisms. The specification of the chemical indicator, or melt pellet in the sealed glass vial is such that the change takes place after achieving the desired sterilization temperature, i.e. 250 F (121 C), 270 F (132 C), or 285 F (141 C), for a defined period of time, thereby providing visual evidence of achieving sterilization temperature. The biological indicator ampule contains a growth promoting culture medium with a pH indicator or a vital dye selected for the indicator organism and spores of known heat resistance. Change of the pH indicator present in the culture medium and turbidity of the media following incubation are evidence for nonsterility, whereas no color change and lack of tubidity after incubation are evidence for sterility.

Three novel applications of this invention are as follows:

1. There are, at present, two generally known means for monitoring the efficacy of a solution sterilization cycle, neither of which is easily carried out. The first and most difficult would be seeding a solution to be sterilized with a known amount of spores, sterilizing the container of solution, recovery and concentration of the spores, and determination of the viability of the spores by various microbiological means.

2. The second generally known method would be to fill a solution flask with culture medium, seed the media with spores of a known resistance, sterilize the container of medium and incubate the solution flask to determine biability of the spores following the sterilization cycle. This method has the disadvantages of requiring immediate use of the culture medium to preclude the growth of adventitious microorganisms and is costly due to the large quantities of culture medium which must be used for such tests. Storage of this type of test container also presents a problem in incubation due to their bulk.

This invention is applicable to monitoring sterilization of solutions by placement of the indicators directly in one or more of the containers of solution being sterilized. Usually one or more of the indicators is employed to monitor a solution sterilization cycle. It provides a compact and easy-to-use sterilization indicator which can be evaluated at the point of use, thereby eliminating the involved procedures and specialized equipment required in the commonly used methods described above.

3. There is presently no acceptable method for evaluating the efficacy of a washer-sterilizer cycle, due to the filling of the sterilizer with water, or water sprays, during a portion of the washer-sterilizer cycle. Such action does destroy the integrity of the packaging commonly used in spore strip type indicators, thus making them susceptible to post sterilization adventitious contamination and false sterilization test results. The system disclosed herein allows the retention of the stability of the biological and chemical indicator until the sterilization cycle is completed. Placement of this combined indicator may be accomplished by various means of anchorage, i.e. tape, clips, or implantation in goods.

Other prior art applications may also be applicable to such a combined chemical and biological system. Such applications might be placement in challenge packs or within other portions of a sterilizer load or such indicators may be used in the evaluation of a dry heat sterilization means.

REFERENCE TO PRIOR ART

United States Patent No. 2,854,384 shows a glass ampule containing two compartments separated by an aperture partition. The aperture is closed by a meltable plug. One compartment contains spores and the other contains a culture media. During sterilization, the plug melts and falls into the culture media allowing the spores to enter the culture media for incubation.

United States Patent No. 3,440,144 discloses an apparatus for testing sterilization including a bag containing a glass ampule with culture medium therein and a spore strip in the bag. After sterilization, the operator can break the glass ampule allowing the culture medium to joint the spores for incubation.

United States Patent No. 3,661,717 shows a unitary indicator much like the preceding indicator.

United States Patent No. 2,998,306 shows a spore strip of a common variety.

None of the forementioned patents combine both an immediate visual indicator and the confirming biological sterilization indicator.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an improved sterilization indicator.

Another object of the invention is to provide a sterilization indicator that is simple and efficient to use.

Another object of the invention is to provide a self-contained indicator system, which is capable of being evaluated and incubated at the point of use, thus eliminating procedures requiring a laboratory and microbiologist.

Another object of the invention is to provide

a sterilization indicator wherein a chemical indicator is isolated from culture media in a sealed glass ampule. The chemical indicator changes when the ambient media has reached a predetermined temperature level and the media containing spores can be subsequently incubated, thereby giving proof positive of the success of the sterilization cycle.

With the above and other objectives in view, the present invention consists of the combination and arrangement of parts hereinafter more fully described, illustrated in the accompanying drawing and more particularly pointed out in the appended claims, it being understood that changes may be made in the form, size, proportions and minor details of construction without departing from the spirit or sacrificing any of the advantages of the invention.

Construction of the indicator is not limited to the chemical indicator being located within the sealed ampule nor within the culture medium. Similar results may also be realized by placement of the chemical indicator externally, either separated or attached to the container of culture medium.

GENERAL DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of the sterilization indicator according to the invention.

Figure 2 is a view of the sterilization indicator in a container of solution to be sterilized.

Figure 3 is an enlarged view of the inner vial of the sterilization indicator showing the meltable pellet therein.

Figure 4 is a view of another embodiment of the invention.

Figure 5 is a view of yet another embodiment of the invention.

Figure 6 is a view of anotehr embodiment of the invention.

Figure 7 is a view of another embodiment of the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Now, with more particular reference to the drawings and Fig. 2, the invention of the sterilizing indicator is supported in the container 10 which contains a solution 11 to be sterilized. The combination chemical and biological indicator 12 is suspended in the solution 11 by means of a cord 19 supported on the closed end 20 of the combination chemical and biological indicator 12 and attached to the cap 17 of the container.

The chemical and biological indicator 12 is made up of an ampule 14, which may be made of glass, sealed with the incubation medium 13 therein, which is a suitable broth that may contain an indicator. Examples of indicators are pH indicators such as phenol red or bromocresol purple or vital dyes, such as triphenyl tetrazolium chloride.

The inner tube 15 is hollow and contains a melt pellet 16. The melt pellet 16 is loosely received on the inside of the tube. The melt pellet 16 is adapted to melt at a predetermined temperature, for example 250 F, 270 F, or 285 F or at some suitable temperature. The broth, or incubation medium, 13 will also contain spores of a predetermined variety, such as *B. stearothermophilus* or some other suitable spores. The melt pellet 16 may be isolated since it may contain chemical materials that might be inhibitory to the spores or cidal to the bacterial growth and, therefore, interfere with the accuracy of the tests if they were not sealed up in the inner tube 15.

When the container 10 of solution to be sterilized is placed in a steam sterilizer or suitable thermal controlled chamber and brought up to temperature, and when the central part of the solution reaches a temperature at which the pellet 16 will melt, the pellet will melt and this will be visible from outside the container. If the melt pellet has not melted, the operator is immediately notified that the cycle was not successful and can resterilize the solution. Then, when the combination chemical and biological indicator 12 is removed from the container 10 and incubated, if the spores are visible, the vital dye will visually turn color and turbid. If a pH indicator is used, viable spores will also cause the solution to change color. If at the end of the incubation time, the spores are not viable, no change in clarity, no change in vital dye or color change will occur and a successful cycle is proven.

The biological test indicator could be used in a washer-sterilizer or other apparatus when it is desirable to get a preliminary indication of the success of a sterilizing cycle. If the pellet is melted, the operator knows immediately that the challenge part of the load has reached sterilizing temperature and can incubate the indicator to verify the success of the cycle. If the pellet is not melted, the load can immediately be resterilized.

In the embodiment of the invention shown in Fig. 4, we show a biological indicator 112, which may be suspended in a solution, such as the solution 11 in Fig. 2. The chemical indicator 112 is made up of an ampule 114, which may be made of glass, sealed at 120 with an incubation medium 113 therein. This incubation medium may be a suitable broth that may contain an indicator. The indicator may be a pH indicator, triphenyl tetrazolium chloride or other suitable indicator. The melt pellet 116 is adapted to melt at a predetermined temperature, for example, 250°F., 270°F., or 285°F. indicating that such temperature has been reached. The broth or incubation medium 113 will contain spores of a suitable variety.

Referring to the embodiment of Fig. 5, this embodiment of the biological chemical indica-

tor 212 has an upper closed end 220 and contains a broth or incubation medium 213 and a melt pellet 216 is supported inside the container 214.

Referring to the embodiment of the invention of Fig. 6, the chemical biological indicator 312 shows a container 314 containing a broth 313 and having a suitable temperature indicating material 316 therein. This could be a filter paper with a temperature sensitive material painted onto it or it could be a material that melts at the predetermined temperature. The enclosure 317 separates the material 316 from the broth 313.

In the embodiment of the invention shown in Fig. 7, we show the chemical and biological indicator 412 containing the incubation medium 413 inside of the outer container 414. The container 416 is affixed to the outside surface of the container 414 and the temperature indicator 417 is housed in the container 416. When the temperature surrounding the container 414 reaches a predetermined temperature, the indicator material 417 will so indicate.

The foregoing specification sets forth the invention in its preferred, practical forms but the structure shown is capable of modification within a range of equivalents without departing from the invention which is to be understood is broadly novel as is commensurate with the appended claims.

CLAIMS

1. A sterilizing indicator comprising,
a transparent container,
said container containing a liquid culture medium containing visible spores,
a temperature indicator,
said temperature indicator being substantially surrounded in said liquid culture medium,
said temperature indicator being adapted to change in appearance when it reaches a predetermined temperature to indicate whether the temperature has reached said predetermined temperature for a predetermined time,
said culture media having indicating means to indicate whether viable spores are present therein when said culture media is incubated.

2. A sterilizing indicator comprising an outer transparent ampule,
said outer ampule containing a liquid culture medium containing living spores,
an innner ampule in said outer ampule,
said inner ampule containing a temperature indicator therein,
said inner ampule being sealed whereby said temperature indicator is isolated from said liquid culture medium,
said temperature indicator being adapted to change in appearance at a predetermined temperature to indicate whether the temperature of said liquid medium inside said inner ampule and in said liquid medium has reached said predetermined temperature,
said liquid culture medium having indicating means therein to indicate whether viable spores are present therein when said culture media is incubated after said outer ampule has been exposed to sterilizing conditions.

3. The sterilizing indicator recited in Claim 1 wherein said indicating means comprises, a pH indicator.

4. The sterilizing indicator recited in Claim 2 wherein said indicating means comprises, a pH indicator.

5. The sterilizing indicator recited in Claim 1 wherein said indicating means comprises, triphenyl tetrazolium chloride.

6. The sterilizing indicator recited in Claim 1 wherein said culture medium contains material that is adapted to have a cloudy appearance as a result of being incubated with said viable spores therein.

7. The sterilizing indicator recited in Claim 6 wherein said culture medium contains material that is adapted to have a cloudy appearance as a result of being incubated with viable spores therein.

8. The sterilizing indicator recited in Claim 7 wherein said viable spores comprise, bacillus stearothermophilus.

9. The sterilizing indicator recited in Claim 8 wherein said viable spores comprise, aerobic or anaerobic spore formers.

10. The sterilizing indicator recited in Claim 9 wherein said viable spores comprise, bacillus stearothermophilus.

11. The sterilizing indicator recited in Claim 10 wherein said viable spores are taken from the group of Bacillus stearothermophilus, Clostridium sporogenes, Clostridium thermosacharolyticum, Bacillus subtilus, or Putrefactive anaerobe 3679.

12. The sterilizing indicator recited in Claim 11 wherein said viable spores comprise, aerobic or anaerobic spore formers.

13. The sterilizing indicator recited in Claim 2 wherein said viable spores are taken from the group of Bacillus stearothermophilus, Clostridium sporogenes, clostridium thermosacharolyticum, Bacillus subtilus, and Putrefactive anaerobe 3679.

14. The sterilizing indicator recited in Claim 1 wherein said temperature indicator is made up of a material that is non-toxic to said spores.

15. The sterilizing indicator recited in Claim 2 wherein said inner ampule is substantially submerged in said culture medium.

16. A method of testing a moist environment in a container to determine if a sterilizing procedure has been successful comprising,
placing in said container a transparent ampule containing a liquid culture medium and spores in said culture medium and a sealed tube containing a melt pellet in said culture medium adapted to melt at a predetermined

temperature,

exposing said container to sterilizing conditions of temperature and time,

if said pellet has melted, incubating said vial for a predetermined time whereby said liquid indicates that said spores have been killed and said procedure has been successful.

17. A method of testing a moist environment in a container to determine if a sterilizing procedure in said container has been successful comprising,

placing in said container an ampule containing a liquid culture medium and spores in said culture medium,

a temperature indicator disposed in said liquid culture medium adapted to change in appearance at a predetermined temperature in said container,

exposing said container to sterilizing conditions of temperature and time.

observing said temperature indicator and if said chemical indicator has changed,

incubating said ampule for a predetermined time whereby said liquid indicates whether said spores have been killed and said procedure has been successful.

18. The method recited in Claim 17 wherein said temperature indicator comprises,

a meltable pellet.

19. The method recited in Claim 18 wherein said indicator is a pellet placed inside said ampule in said culture medium.

20. The method of Claim 19 as described.

21. A sterilizing indiciator substantially as hereinbefore described with reference to the accompanying drawings.

22. A method of of testing a moist environment in a container to determine whether a sterilizing procedure has been successful substantially as hereinbefore described with reference to the accompanying drawings.

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